



UNITED STATES PATENT AND TRADEMARK OFFICE

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COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

James J. Sales  
Eli Lilly and Company  
Patent Division/jjs Lilly Corporate Center  
Indianapolis IN 46285

Re: **REEXAM UNIT**  
Patent Term Extension  
Application for  
U.S. Patent No. 4,418,068

#22

Dear Mr. Sales:

A order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,418,068 for a period of one-year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: <http://www.fda.gov/cder/orange/patdecl.pdf>.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: EVISTA®  
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Eli Lilly and Company  
Request for Patent Term Extension  
U.S. Patent No. 4,418,068

:  
: **ORDER GRANTING**  
: **INTERIM EXTENSION**

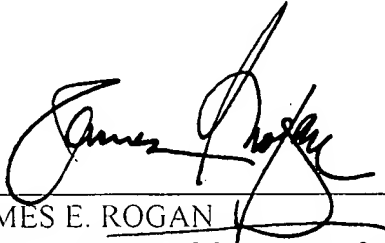
Eli Lilly and Company, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,418,068, filed an application for patent term extension under 35 U.S.C. § 156. An extension of 1,103 days is requested, and an interim extension under 35 U.S.C. § 156(e)(2) has been previously granted for a period of one year. The patent is eligible for an extension of at least two years. The expiration date of the patent, as previously extended, is April 3, 2002. The patent claims the active ingredient raloxifene hydrochloride in the human drug product "EVISTA®". The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, as previously extended, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,418,068 is granted for a period of one year from the extended expiration date of the patent, until April 3, 2003.

MAR - 7 2002

Date

  
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JAMES E. ROGAN  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office